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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,226	05/08/2001	Jeffry G. Weers	0073.00	4017

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EXAMINER	
WELLS, LAUREN Q	

ART UNIT	PAPER NUMBER
1617	18

DATE MAILED: 07/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/851,226	WEERS ET AL.	
	Examiner	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE f this c mmunication appears n th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8,9,11-32,44-62 and 64-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8,9,11-32,44-62 and 64-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-5, 8-9, 11-32, 44-71 are pending. The Amendment filed 5/13/03, Paper No. 17, amended claims 1, 31, 32, 44, 59, 64, 65, and cancelled claim 63.

The IDS filed 6/3/02, Paper No. 5, has been received. However, none of the references on the IDS have been provided. The Examiner called the attorney on 6/23/03 to request these references, however, the Examiner was unable to obtain the references.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/13/03 has been entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 8-22, 27-32, and 44-52, 59-62, 64-71 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

claims 1-5, 7-23, 25, 27, 28-30, 34-37, 41-45 of copending Application No. 09/568818. Although the conflicting claims are not identical, they are not patentably distinct from each other. '818 teaches a microparticle comprised of a metal ion-lipid complex and particulate compositions thereof. '818 teaches calcium as its metal ion and phoshatidylcholine (a saturated phospholipid) as its lipid complex. '818 fails to teach an amount effective to increase the gel-to-liquid crystal transition temperature of the particle compared to particles without the divalent cation, wherein the particulate composition is storage stable. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to teach such a limitation in the invention of '818 because '818 and the instant claims teach the same composition comprising the same constituents. Thus, the composition of '818 must have these properties, as a compounds and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 8-32, 44-62, 64-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weers et al. (6,309,623) in view of Materne et al. (GB 2065659).

The instant invention is directed toward a particulate composition comprising particles comprising a saturated, zwitterionic phospholipid and a polyvalent cation at a molar ratio of polyvalent cation to phospholipid of at least 0.05 effective to increase the gel-to-liquid crystal transition temperature of the particle compared to particles without the polyvalent cation, wherein the particulate composition is storage stable, and methods of administering such a composition to the pulmonary system of a patient.

Weers et al. teach a stable respiratory dispersion for pulmonary delivery of one ore more bioactive agents comprising a suspension medium having dispersed therein a plurality of perforated microstructures having a mean aerodynamic diameter of less than 5 micrometers and comprising at least one bioactive agent. The perforated microstructures are taught as comprising 1-90% surfactants, wherein surfactants are selected from saturated phospholipids, nonionic detergents, nonionic block copolymers, ionic surfactants, and combinations thereof. Dipalmitoylphosphatidylcholine is taught as a saturated phospholipid surfactant, and poloxamer is taught as a surfactant. Inorganic salts such as calcium chloride are taught as optional excipients, which adjust the pH. Budesonide, fluticasone propionate, salmeterol, and formoterol are taught as bioactive agents that can comprise from 5-90% of the composition. Taught are structural matrices comprising the perforated microstructures, wherein polyvinyl alcohols, polyvinyl pyrrolidones, and polysaccharides are taught as part of the matrix. The perforated microparticles are taught as hollow and/or porous. The suspension medium of the microparticles is taught as a non-aqueous medium. The density of the particles is taught as less than 0.05g/cm3. Taught is administration of the compounds in composition to the lung of a patient in need of such treatment, using a metered dose inhaler. The composition has a gel to liquid crystal phase

transition greater than about 40 C. The reference lacks an exemplification of a composition comprising saturated phospholipid and divalent cation, and a teaching of the ratio of cation to phospholipid. See Col. 4, line 5-Col. 8, line 65; Col. 11, lines 25-42; Col. 16, line 28-Col. 20, line 20; Col. 24, line 56-Col. 25, line 5; Col. 40, line 54-Col. 41, line 55.

Materne teaches calcium phosphatidycholine chloride for pharmaceutical preparations. A ratio of 0.5:1-2:1 of cation to phospholipid is taught. Such as ratio is taught as highly stable for pharmaceutical formulation. See pg. 1, lines 80-129.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to exemplify a suspension medium comprising calcium chloride and dipalmitoylphosphatidyl choline because Weers et al. exemplify a composition comprising dipalmitoylphosphatidyl choline and they teach that adding salts fine tunes the stabilized dispersions for maximum life and ease of administration.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the ratio of calcium to dipalmitoylphosphatidyl choline as at least 0.05, as taught by Materne, because of the expectation of achieving a highly stable pharmaceutical microparticle formulation and because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Since the microparticles taught by the combination of Weers et al. and Materne et al. are the same as those taught by the instant claims, the microparticles of Weers et al. must have the same gel-to-liquid transition temperatures and storage stability as the microparticles of the instant invention.

Regarding Applicant's functional limitations, attention is respectfully directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468.

Claims 23-25 are directed to a future intended use of the composition. Thus, these claims are not given patentable weight.

The recitation for delivery to the pulmonary system has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Response to Arguments

Applicant argues, "Weers et al. is silent as to any teaching of molar ratios as claimed". This argument is not persuasive. The Examiner respectfully directs the Applicant to the combination of Weers et al. and Materne et al., as applied above, wherein the combination of these references teaches the molar ratio.

Applicant argues, "the unexpected results attributed to the addition of calcium chloride in such amounts are nowhere disclosed or suggested in Weers et al.". This argument is not persuasive. First, the Examiner respectfully points out that the instant claims do not recite any unexpected results. Second, the Examiner respectfully points out that Applicant has not submitted a declaration of unexpected results in conjunction with Weers et al.

Applicant argues that he has achieved unexpected results as evidenced by pages 8 and 9 of the specification and the declaration filed 12/2/02, Paper No. 12. This argument is not persuasive. The Examiner respectfully directs the Applicant to the guidelines for showing unexpected results. It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, it is respectfully pointed out that Applicant has not provided

unexpected results over the closest prior art (Weers et al.) and has not provided data that is commensurate in scope with the instant claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
July 8, 2003

RUSSELL TRAVERS
PRIMARY EXAMINER